Attorney Docket No.: 098501-0235299

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1-37. (Canceled)

- 38. (Currently Amended) A method for obtaining the production of a fertilizable oocyte within a program of controlled ovarian stimulation for assisted reproduction techniques (COS/ART) consisting essentially of:
 - (a) administering to a female human selected for controlled ovarian stimulation, a combination single dose of luteinizing hormone (LH) and a single dose of follicle stimulating hormone (FSH) to induce follicle growth, wherein the dose of LH and FSH remains the same throughout the treatment period, and
 - (b) administering an amount of a luteinizing hormone releasing hormone (LHRH) antagonist selected from the group consisting of Ganirelix, Antarelix, Antide, Azaline B, Ramorelix, A-76154, Nal-Glu, 88-88, Cetrorelix, D23980, and D-24824, to prevent a premature LH surge, wherein the LHRH antagonist is administered in a single or dual dosage regimen of 3 mg per dose beginning on menstruation cycle day 1 to 10 as one or two, daily, 3mg doses, beginning on menstrual cycle day 1 and continuing through day 10;

wherein said method begins on a day selected from the group consisting of day 1 and day 2 of a menstrual cycle, and day in a late luteal phase of the previous menstrual cycle;

wherein follicular growth occurs in the absence of a LH surge, a fertilizable oocyte is produced, ovulation occurs between day 9 and 20 of the menstruation cycle, and the dosage regimen of the LHRH antagonist is selected so as to suppress endogenous LH secretion, but does not suppress endogenous FSH secretion, which is maintained at a natural level and individual estrogen development is not affected.

2

401521330v1

Attorney Docket No.: 098501-0235299

39. (Previously presented) The method of claim 38, wherein step (a) comprises administering human menopausal gonadotropin (HMG) to induce follicle growth.

40-41. (Canceled)

42. (Previously Presented) The method of claim 38, wherein the LHRH antagonist is administered by subcutaneous injection.

43. (Canceled)

- 44. (Previously presented) The method of claim 38, wherein the LHRH antagonist is administered starting on cycle day 4 to 8.
- 45. (Previously Presented) The method of claim 38, wherein the LHRH antagonist is administered starting on cycle day 6 to 10 and ovulation occurs between day 9-16 of the menstruation cycle.
- 46. (Previously Presented) The method of claim 38, wherein ovulation occurs within 6.5 days following administration of a single or second dose of the LHRH antagonist.
 - 47. (Cancelled)
- 48. (Previously Presented) The method of claim 38, wherein ovulation is induced by administering a hormone or hormone agonist in order to induce ovulation.
- 49. (Previously Presented) The method of claim 38, wherein ovulation is induced by administering a hormone or hormone agonist selected from the group consisting of native LH, recombinant LH, an LHRH agonist, and HCG.
- 50. (Previously Presented) The method of claim 38, wherein the LHRH antagonist is Cetrorelix.
- 51. (Currently Amended) A method for obtaining the production of a fertilizable oocyte within a program of COS/ART consisting essentially of:

Attorney Docket No.: 098501-0235299

(a) administering to a female human selected for controlled ovarian stimulation, a single dose of human menopausal gonadotropin (HMG) to induce follicle growth, and

(b) administering <u>an amount of</u> Cetrorelix to prevent a premature LH surge, wherein Cetrorelix is administered in a single or dual dosage regimen of 3 mg per dose beginning on menstruation cycle day 1 to 10 as one or two, daily, 3mg doses, beginning on menstrual cycle day 1 and continuing through day 10;

wherein said method begins on a day selected from the group consisting of day 1 and day 2 of a menstrual cycle, and day in a late luteal phase of the previous menstrual cycle;

wherein follicular growth occurs in the absence of a LH surge, a fertilizable oocyte is produced, ovulation occurs between day 9 and 20 of the menstruation cycle, and the dosage regimen of the Cetrorelix is selected so as to suppress endogenous LH secretion, but does not suppress endogenous FSH secretion, which is maintained at a natural level and individual estrogen development is not affected.

52-55. (Canceled)

- 56. (Previously Presented) The method of claim 51, wherein the Cetrorelix is administered starting on cycle day 4 to 8.
- 57. (Previously Presented) The method of claim 51, wherein Cetrorelix is administered starting on cycle day 6 to 10 and ovulation occurs between day 9-16 of the menstruation cycle.
- 58. (Previously Presented) The method of claim 51, wherein ovulation occurs within 6.5 days following administration of a single or second dose of Cetrorelix.
 - 59. (Cancelled)

Attorney Docket No.: 098501-0235299

60. (Previously Presented) The method of claim 51, wherein ovulation is induced by administering a hormone or hormone agonist selected from the group consisting of native LH, recombinant LH, an LHRH agonist, and HCG.

- 61. (Currently Amended) A method for obtaining the production of a fertilizable oocyte within a program of COS/ART comprising:
- (a) administering to a female human selected for controlled ovarian stimulation, combination a single dose of luteinizing hormone (LH) and a single dose follicle stimulating hormone (FSH) to induce follicle growth; and
- (b) administering an amount of an LHRH antagonist selected from the group consisting of Ganirelix, Antarelix, Antide, Azaline B, Ramorelix, A-76154, Nal-Glu, 88-88, Cetrorelix, D-23980, and D-24824 to prevent a premature LH surge;

wherein the LHRH antagonist is administered in a single or dual dosage regimen of 3 mg per dose beginning on menstruation cycle day 1 to 10 as one or two, daily, 3mg doses, beginning on menstrual cycle day 1 and continuing through day 10;

wherein said method begins on a day selected from the group consisting of day 1 and day 2 of a menstrual cycle, and day in a late luteal phase of the previous menstrual cycle;

wherein follicular growth occurs in the absence of a LH surge, a fertilizable oocyte is produced, ovulation occurs normally between day 9 and 20 of the menstruation cycle without the administration of a hormone or hormone agonist to induce ovulation,

wherein said amount of LHRH antagonist is sufficient to suppress LH,

wherein said amount of LHRH antagonist does not suppress endogenous FSH secretion which is maintained at a natural level and individual estrogen development is not affected.

- 62. (Previously Presented) The method of claim 61, wherein the dosage of LHRH antagonist is in the range of 2-6 mg per dose.
- 63. (Previously Presented) The method of claim 61, wherein the dosage of LHRH antagonist is 3 mg per dose.

Attorney Docket No.: 098501-0235299

64. (Canceled)

65. (Previously Presented) The method of claim 61, wherein the LHRH antagonist is

administered by subcutaneous injection.

66. (Canceled)

67. (Previously Presented) The method of claim 61, wherein the LHRH antagonist is

administered starting on cycle day 4 to 8.

68. (Previously Presented) The method of claim 61, wherein the LHRH antagonist is

administered starting on cycle day 6 to 10 and ovulation occurs between day 9-16 of the

menstruation cycle.

69. (Previously Presented) The method of claim 61, wherein ovulation occurs within

6.5 days following administration of a single or second dose of the LHRH antagonist.

70. (Previously Presented) The method of claim 61, wherein step (a) comprises

administering human menopausal gonadotropin (HMG) to induce follicle growth.

71. (Canceled)

72. (Previously Presented) The method of claim 61, wherein the LHRH antagonist is

Cetrorelix.

73. (Previously Presented) The method of claim 70, wherein the LHRH antagonist is

Cetrorelix.

74. (Previously Presented) The method of claim 73, wherein the dosage of Cetrorelix

is in the range of 2-6 mg per dose.

75. (Previously Presented) The method of claim 73, wherein the dosage of LHRH

antagonist is 3 mg per dose.

76-77. (Canceled)

Attorney Docket No.: 098501-0235299

78. (Previously Presented) The method of claim 73, wherein the LHRH antagonist is administered starting on cycle day 4 to 8.

- 79. (Previously Presented) The method of claim 73, wherein Cetrorelix is administered starting on cycle day 6 to 10 and ovulation occurs between day 9-16 of the menstruation cycle.
- 80. (Previously Presented) The method of claim 73, wherein ovulation occurs within 6.5 days following administration of a single or second dose of Cetrorelix.

81-82. (Canceled)

- 83. (Currently amended) A method for obtaining the production of a fertilizable oocyte within a program of controlled ovarian stimulation for assisted reproduction techniques (COS/ART) comprising
- (a) administering to a female human selected for controlled ovarian stimulation, a combination single dose of luteinizing hormone (LH) and a single dose of follicle stimulating hormone (FSH) to induce follicle growth,
- (b) administering an amount of an LHRH antagonist selected from the group consisting of Ganirelix, Antarelix, Antide, Azaline B, Ramorelix, A-76154, Nal-Glu, 88-88, Cetrorelix, D-23980, and D-24824 to prevent a premature LH surge, wherein the LHRH antagonist is administered in a dosage regimen of daily doses of 0.25 mg/day for multiple days until ovulation,

wherein said method begins on a day selected from the group consisting of day 1 and day 2 of a menstrual cycle, and day in a late luteal phase of the previous menstrual cycle;

wherein the LHRH antagonist is administered daily beginning on menstruation cycle day 1 to 10, wherein the follicular growth occurs in the absence of a LH surge, a fertilizable oocyte is produced, ovulation occurs between day 9 and 20 of the menstruation cycle, and the LHRH antagonist is sufficient to suppress LH, while FSH secretion is maintained at a natural level and individual estrogen development is not affected.

Attorney Docket No.: 098501-0235299

84. (Previously Presented) The method of claim 83, wherein the LHRH antagonist is administered by subcutaneous injection.

85. (Canceled)

- 86. (Previously Presented) The method of claim 83, wherein the LHRH antagonist is administered starting cycle on day 4 to 8.
- 87. (Previously Presented) The method of claim 83, wherein a daily dose of the LHRH antagonist is administered for 3 to 14 days.
- 88. (Previously Presented) The method of claim 83, wherein a daily dose of the LHRH antagonist is administered for 3 to 7 days.
 - 89. (Cancelled)
- 90. (Previously Presented) The method of claim 83, wherein ovulation is induced by administering a hormone or hormone agonist selected from the group consisting of native LH, recombinant LH, an LHRH agonist, and HCG.
- 91. (Previously Presented) The method of claim 83, wherein the LHRH antagonist is Cetrorelix.
- 92. (Currently Amended) A method for obtaining the production of a fertilizable oocyte within a program of COS/ART comprising:
- (a) administering to a female human selected for controlled ovarian stimulation, a single dose of human menopausal gonadotropin (HMG) to induce follicle growth, and;
- (b) administering an amount of Cetrorelix to prevent a premature LH surge, wherein Cetrorelix is subcutaneously administered in a dosage regimen of daily doses of 0.25 mg per day for multiple days;

wherein said method begins on a day selected from the group consisting of day 1 and day 2 of a menstrual cycle, and day in a late luteal phase of the previous menstrual cycle;

Attorney Docket No.: 098501-0235299

wherein follicular growth occurs in the aence absence of a LH surge, a fertilizable oocyte is produced, ovulation occurs between day 9 and 20 of the menstruation cycle, and the Cetrorelix is sufficient to suppress LH, while FSH secretion is maintained at a natural level and individual estrogen development is not affected.

- 93. (Canceled)
- 94. (Previously Presented) The method of claim 92, wherein Cetrorelix is administered starting on cycle day 4 to 8.
- 95. (Previously Presented) The method of claim 92, wherein a daily dose of Cetrorelix is administered for 3 to 14 days.
- 96. (Previously Presented) The method of claim 92, wherein a daily dose of Cetrorelix is administered for 3 to 7 days.
 - 97. (Cancelled)
- 98. (Previously Presented) The method of claim 92, wherein ovulation is induced by administering a hormone or hormone agonist selected from the group consisting of native LH, recombinant LH, an LHRH agonist, and HCG.
- 99. (Currently Amended) A method for obtaining the production of a fertilizable oocyte within a program of controlled ovarian stimulation for assisted reproduction techniques (COS/ART) comprising
- (a) administering to a female human selected for controlled ovarian stimulation, a combination single dose of luteinizing hormone (LH) and a single dose of follicle stimulating hormone (FSH) to induce follicle growth; and
- (b) administering an amount of an LHRH antagonist selected from the group consisting of Ganirelix, Antarelix, Antide, Azaline B, Ramorelix, A-76154, Nal-Glu, 88-88, Cetrorelix, D-23980, and D-24824 to prevent a premature LH surge, wherein the LHRH antagonist is administered in a dosage regimen of daily doses of from 0.25 to 0.5 mg per day for multiple days;

9

Attorney Docket No.: 098501-0235299

wherein said method begins on a day selected from the group consisting of day 1 and day 2 of a menstrual cycle, and day in a late luteal phase of the previous menstrual cycle;

wherein follicular growth occurs in the absence of a LH surge, a fertilizable oocyte is produced, ovulation occurs normally between day 9 and 20 of the menstruation cycle without the administration of a hormone or hormone agonist to induce ovulation, and the LHRH antagonist is sufficient to suppress LH, while FSH secretion is maintained at a natural level and individual estrogen development is not affected.

- 100. (Previously Presented) The method of claim 99, wherein the LHRH antagonist is administered by subcutaneous injection.
 - 101. (Canceled)
- 102. (Previously Presented) The method of claim 99, wherein the LHRH antagonist is administered starting cycle day 4 to 8.
- 103. (Previously Presented) The method of claim 99, wherein a daily dose of the LHRH antagonist is administered for 3 to 14 days.
- 104. (Previously Presented) The method of claim 99, wherein a daily dose of the LHRH antagonist is administered for 3 to 7 days.
- 105. (Previously Presented) The method of claim 99, wherein step (a) comprises administering human menopausal gonadotropin (HMG) to induce follicle growth.
 - 106. (Canceled)
- 107. (Previously Presented) The method of claim 99, wherein the LHRH antagonist is Cetrorelix.
- 108. (Previously Presented) The method of claim 105, wherein the LHRH antagonist is Cetrorelix.
 - 109. (Canceled)

Attorney Docket No.: 098501-0235299

110. (Previously Presented) The method of claim 108, wherein Cetrorelix is administered starting on cycle day 4 to 8.

- 111. (Previously Presented) The method of claim 108, wherein a daily dose of Cetrorelix is administered for 3 to 14 days.
- 112. (Previously Presented) The method of claim 108, wherein a daily dose of Cetrorelix is administered for 3 to 7 days.
- 113. (Previously Presented) The method of claim 108, wherein ovulation occurs normally, without the administration of a hormone or hormone agonist to induce ovulation.
- 114. (Previously Presented) The method of claim 108, wherein ovulation is induced by administering a hormone or hormone agonist selected from the group consisting of native LH, and recombinant LH.
- 115. (Previously Presented) A method for obtaining the production of a fertilizable oocyte within a program of assisted reproduction techniques comprising in a female human selected for controlled ovarian stimulation.
- (a) allowing normal follicular growth and development to proceed in the absence of stimulation by an exogenous gonadotropin;
- (b) administering an amount of an LHRH antagonist selected from the group consisting of Ganirelix, Antarelix, Antide, Azaline B, Ramorelix, A-76154, Nal-Glu, 88-88, Cetrorelix, D-23980, and D-24824, in a dosage regimen that prevents a premature LH surge, beginning on menstruation cycle day 1 to 10;

wherein said method begins on a day selected from the group consisting of day 1 and day 2 of a menstrual cycle, and day in a late luteal phase of the previous menstrual cycle;

wherein follicular growth and development proceeds in the absence of a LH surge and a fertilizable oocyte is produced, ovulation occurs between day 9 and 20 of the menstruation cycle,

Attorney Docket No.: 098501-0235299

wherein said amount of said LHRH antagonist is sufficient to suppress LH,

wherein said amount of said LHRH antagonist does not suppress endogenous FSH secretion, which is maintained at a natural level and individual estrogen development is not affected.

116. (Previously Presented) The method of claim 115, wherein the LHRH antagonist is administered by subcutaneous injection.

117. (Canceled)

118. (Previously Presented) The method of claim 115, wherein the LHRH antagonist is administered starting on cycle day 4 to 8.

119. (Previously Presented) The method of claim 115, wherein the method is performed on a patient in whom follicular growth is inadequate due to previous treatment with an LHRH antagonist, and step (a) comprises allowing normal follicular growth and development to proceed in the absence of treatment of the patient with an LHRH antagonist and in the absence of stimulation by an exogenous gonadotropin.

120. (Canceled)

121. (Cancelled)

122. (Previously Presented) The method of claim 115, wherein ovulation is induced by administering a hormone or hormone agonist in order to induce ovulation.

123. (Previously Presented) The method of claim 115, wherein ovulation is induced by administering a hormone or hormone agonist selected from the group consisting of native LH, recombinant LH, an LHRH agonist, and HCG.

124-125. (Canceled)

126. (Previously Presented) The method of claim 115, wherein the LHRH antagonist is Cetrorelix.

Attorney Docket No.: 098501-0235299

127. (Previously Presented) The method of claim 115, wherein a fertilizable oocyte is produced within a program of extracorporeal fertilization by sperm injection.

- 128. (Previously Presented) The method of claim 115, wherein a fertilizable oocyte is produced within a program of extracorporeal fertilization by *in vitro* fertilization.
- 129. (Previously Presented) The method of claim 115, wherein the LHRH antagonist is administered in a single or dual dosage regimen of 1 to 10 mg per dose.
- 130. (Previously Presented) The method of claim 129, wherein the dosage of LHRH antagonist is in the range of 2-6 mg per dose.
- 131. (Previously Presented) The method of claim 129, wherein the LHRH antagonist is administered starting on cycle day 6 to 10 and ovulation occurs between day 9 to 16 of the menstruation cycle.
- 132. (Previously Presented) The method of claim 129, wherein ovulation occurs within 6.5 days following administration of a single or second dose of the LHRH antagonist.
- 133. (Previously Presented) The method of claim 129, wherein the LHRH antagonist is Cetrorelix.
- 134. (Previously Presented) The method of claim 115, wherein the LHRH antagonist is administered in a dosage regimen of daily doses of from 0.25 to 0.5 mg/day for multiple days.
- 135. (Previously Presented) The method of claim 134, wherein a daily dose of the LHRH antagonist is administered for 3 to 14 days.
- 136. (Previously Presented) The method of claim 134, wherein a daily dose of the LHRH antagonist is administered for 3 to 7 days.
- 137. (Previously Presented) The method of claim 135, wherein the LHRH antagonist is Cetrorelix.

Attorney Docket No.: 098501-0235299

138. (Previously Presented) The method of claim 137, wherein the daily dose of Cetrorelix is 0.25 mg/day or 0.5 mg/day.

- 139. (Previously Presented) The method of claim 83, wherein step (a) comprises administering human menopausal gonadotropin (HMG) to induce follicle growth.
- 140. (Previously Presented) The method of claim 99, wherein the LHRH antagonist is Cetrorelix and the daily dose is 0.25 mg/day or 0.5 mg/day.
- 141. (Previously Presented) The method of claim 108, wherein the daily dose of Cetrorelix is 0.25 mg/day or 0.5 mg/day.